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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO
09/675,020	09/28/2000	Robert S. Matson	2014-181	7650
22471	7590 09/21/2004		EXAM	INER
	EGAL DEPARTMENT, COULTER, INC.	DAVIS, DEBORAH A		
	4300 N. HARBOR BOULEVARD		ART UNIT	PAPER NUMBER
BOX 3100 FULLERTON, CA 92834-3100			1641	

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
	09/675,020	MATSON ET AL.
Office Action Summary	Examiner	Art Unit
	Deborah A Davis	1641
The MAILING DATE of this communication	appears on the cover sheet w	rith the correspondence address
Period for Reply	'DLV IC OFT TO EVOIDE . A	AONTHAN THOM
A SHORTENED STATUTORY PERIOD FOR RE THE MAILING DATE OF THIS COMMUNICATIO  - Extensions of time may be available under the provisions of 37 CFF after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a  - If NO period for reply is specified above, the maximum statutory per  - Failure to reply within the set or extended period for reply will, by state Any reply received by the Office later than three months after the management of the property of the prop	NN. R 1.136(a). In no event, however, may a reply within the statutory minimum of thir riod will apply and will expire SIX (6) MON atute, cause the application to become Af	reply be timely filed  ty (30) days will be considered timely.  THS from the mailing date of this communication.
Status		
1) Responsive to communication(s) filed on 24	4 May 2004.	
The state of the s	This action is non-final.	
3) Since this application is in condition for allow	wance except for formal matt	ters, prosecution as to the merits is
closed in accordance with the practice unde	er <i>Ex parte Quayle</i> , 1935 C.D	). 11, 453 O.G. 213.
Disposition of Claims		
4)⊠ Claim(s) <u>1-25,31 and 32</u> is/are pending in th	he application	
4a) Of the above claim(s) is/are withd	• •	
5) Claim(s) is/are allowed.		
6)⊠ Claim(s) <u>1-25 and 31-32</u> is/are rejected.		
7) Claim(s) is/are objected to.		
8) Claim(s) are subject to restriction and	d/or election requirement.	
Application Papers		
9) The specification is objected to by the Exami	iner.	
10) The drawing(s) filed on is/are: a) a		by the Examiner.
Applicant may not request that any objection to the		
Replacement drawing sheet(s) including the corre		
11) The oath or declaration is objected to by the	Examiner. Note the attached	Office Action or form PTO-152.
Priority under 35 U.S.C. § 119		
12) Acknowledgment is made of a claim for foreign	an priority under 35 U.S.C. &	119(a)-(d) or (f)
a) ☐ All b) ☐ Some * c) ☐ None of:	griphianily animal de didicity	1.0(a) (a) 6. (1).
1. Certified copies of the priority docume	ents have been received.	
2. Certified copies of the priority docume	ents have been received in Ap	oplication No
<ol><li>Copies of the certified copies of the pr</li></ol>	riority documents have been i	received in this National Stage
application from the International Bure		
* See the attached detailed Office action for a list	st of the certified copies not r	received.
Attachment(s)		
Notice of References Cited (PTO-892) Notice of Draftsperson's Patent Drawing Review (PTO-948)	4) 🔲 Interview Su Paner No(s)	ummary (PTO-413) /Mail Date
() Information Disclosure Statement(s) (PTO-1449 or PTO/SB/0.  Paper No(s)/Mail Date		formal Patent Application (PTO-152)

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#### **DETAILED ACTION**

#### Continued Examination Under 37 CFR 1.114

- 1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 24, 20054 has been entered.
- 2. Applicant's response to the Office Action mailed on May 03, 2004 has been acknowledged. Claims 1-25 and 31-32. Claims 26-30 are canceled.

## Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35
 U.S.C. 102 that form the basis for the rejections under this section made in this
 Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors

Protection Act of 1999 (AIPA) do not apply to the examination of this application
as the application being examined was not (1) filed on or after November 29,
2000, or (2) voluntarily published under 35 U.S.C. 122(b). Therefore, this

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application is examined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-2, 4-5, 6-15, 19, 22 and 31-32 are rejected under 35
 U.S.C. 102(e) as being anticipated by Moring et al (USP#6,159,368).

Moring et al anticipates the instant claims by disclosing an assembly for a microarray assay device (see Figure 2). The microplate has a plurality of discrete array formation areas each formed of flexible material (col. 14, lines 1-28). Moring et al discloses filter elements that form the bottom of the microplate wells made of material that lacks rigidity (col. 14, lines 24-28). Barriers are formed between the array formation areas (see Figure 2). Moring et al discloses a vacuum fixture defining a top surface and an interior chamber connectable to a vacuum source (col. 22, lines 5-13) with a plurality of orifices connected to the interior chamber and opening at the top surface corresponding to the array formation areas when the microplate is mounted on the top surface of the vacuum fixture (col. 22, lines 17-21). Moring et al discloses apertures (orifices) that are extended through the surface of the microplate (see Figure 3, #28) that corresponds to array formation areas. The microplate is located on top of the vacuum chamber (see Figure 2, #24). Barriers such as filter elements are formed for flexible material (col. 17, lines 25-27). The microplate comprises a support plate, a flat substrate formed of the flexible material (col. 14, lines 29-34) over the support plate (Figure 2, #24) and a gasket defining a plurality of holes over the substrate and gasket contains an array formation area (see Figure 2, #44, #32) as recited in claim 6. The microplate has a rigid frame attached to the

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flexible material (Figure 2, #38) as recited in claim 7. Alternatively, well can be formed in a plurality of strips arranged side by side within a frame designed to hold strips (col. 12, lines 14-31) as recited in claim 8. Moring et al discloses a plurality of biorecognition materials in the microplate array (col. 30, lines 30-34) as recited in claims 9-12. Moring et al discloses a cover plate that contains a nodule (cap) for each well (col. 28, lines 1-5) as recited in claim 19. The microplate has a tray (plates) that is formed of flexible material using conventional means of injection molding (col. 11, lines 55-68).

## Claim Rejections - 35 USC § 103

- 5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
- 6. Claims 3, and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moring et al in view of Mathus et al (USP#5,858,309).

The teachings of Moring et al are set forth above and differ from the instant claims in not pointing out the material thickness, height, in the microplate and flexural modulus; hardness and specific temperature as recited in claim 18.

However, Mathus et al teaches microplates and methods for manufacturing microplates. This microplate is designed to allow UV radiation to pass through the bottom of the wells (See abstract). In the detailed description of

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the invention, a microplate with a material thickness of 7.5mils is used to obtain the desired wavelength (col. 4, lines 55-65).

It would have been obvious to one of ordinary skill in the art to vary the thickness in the microplate of Moring et al as taught by Mathus et al to allow UV radiation to pass through the bottom of the wells as to obtain the desired wavelength. With respect to claim18, it would have been further obvious to one of ordinary skill in the art to vary temperature, hardness and flexibility in microplate assemblies because they are routine optimizations that are almost always determined in material fabrication. Unless the result obtained in the instant application is a significant and unexpected difference over the prior art, it would have been obvious for one of ordinary skill in the art to employ these modifications as a means of optimizing the devices provided by the art. With respect to the barriers having a height of less than 4mm is considered a matter of design choice. A change in size is generally recognized as being within the level of ordinary skill in the art. In re Rose, 105 USPQ 237 (CCPA 1955).

## Claim Rejections - 35 USC § 103

- 7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:
  - (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

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8. Claims 20-21 and 23-24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Moring et al in view of Mohan et al (USP# 5,888,830).

The teachings of Moring et al are set forth above and differ from the instant claims in not teaching such limitations as a lid that has a plurality of caps with inlet/outlet ports, a temperature control element and a vacuum fixture.

However, Mohan et al teaches a capping plate with a plurality of caps that corresponds to an array area and seals the reaction vessel. Each cap has access to an inlet and outlet port and the microplate assembly has a temperature control element (See Figure 1 and 1A). The microplate assemble has a vacuum fixture on the surface of the interior chamber (See Figure 1). A cleavage section that has a chamber containing a plurality of vial ports, each holding separate vials with inlet and outlet ports for connecting the chamber to a vacuum supply (col. 2, lines 55-65). The temperature control element can be used to heat or cool fluid that circulates through channels in the plate (col. 13, lines 1-7). The microplate assembly also provides for a silicon heating pad that is sandwiched between the top heater block and the bottom heater block and is connected by leads to a heater control (See Figure 1) which maintains the desired heat level (col. 12, lines 59-63). Such a system would provide an improved apparatus for performing multiple chemical reactions on a solid support in a parallel fashion in a simple and easy manner (col. 1, lines 52-64).

It would have been obvious to one of ordinary skill in the art to incorporate the capping plate of Mohan et al into the microplate of Moring et al to seal the reaction vessel. The vacuum fixture taught by Mohan et al is also obvious for

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connecting the chamber to a vacuum supply to assist in the flow of fluid. It would have been further obvious to incorporate a heater control element to maintain a desired heat level since such a heating element is usually required for chemical reactions. One of ordinary skill in the art would have also been motivated to add the additional features taught by Mohan et al into the microplate assembly of Moring et al in order to provide an improved apparatus for performing multiple chemical reactions on a solid support in a parallel fashion in a simple and easy manner.

9. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Moring et al in view of Stylli et al (USP#5,985,214).

The teachings of Moring et al are set forth above and differ from the instant claims in failing to teach a peristaltic pump.

However, Stylli et al teaches in his present invention systems and methods that utilize automated and integratable workstations for identifying chemicals having useful activity (See abstract). When live cells are being dispensed, it may be necessary to provide re-circulation of the cell culture through a fluid system in order to prevent adhesion or pooling of the cells, which can be accomplished by a peristaltic pump (col. 59, lines 20-32).

It would have been obvious to one of ordinary skill in the art to modify the microplate of Moring et al to include a peristaltic pump in as taught by Stylli et al to provide re-circulation of the cell culture that would prevent adhesion or pooling of the cells.

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### Response to Arguments

10. Applicant's argument that the reference of Moring fails to teach that each orifice is connected directly to both the top surface and the interior chamber is not found persusasive.

In response to applicant's argument, the reference of Moring teaches that the orifices in (Figure 3 #28) are connected to the top surface of the collection plate that extends through the bottom surface of the plate, which is connected to the interior chamber.

11. Applicant argument that the reference of Moring et al cannot make the instant claim 1 obvious is not found persuasive.

In response to applicant's argument, claim 1 has been rejected over Moring et al as being anticipated under 102, not 103.

12. Applicant's argument that the instant invention has several advantages that facilitate high-resolution printing and reading of the microarrays is noted, but language of language of claim one is still anticipated by Moring et al. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

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Therefore, the structural elements of Moring et al are capable of the providing the same advantages of the instant invention.

- 13. Applicant's argument that the orifice of Moring et al would presumably prohibit alternating pressures, since alternating positive and negative pressure could cause the flow through in the closed bottom well 26 to back up into the filter element 8a (Moring; Figure 3) is not found persuasive because applicant provides no support for this assumption.
- 14. Applicant argument that Moring does not anticipate claim 22 because it requires the similar limitation that each of the orfices connects to both the top surface and the interior chamber is not found persusasive for reasons above of the rejected claim 1.
- 15. Applicant's argument that the reference of Mathus cannot remedy the defect of Moring because claims 3, and 16-18 depend from claim 1 which is not anticipated by Moring. Applicant further argues the Mathus neither teaches nor suggests orfices that are connected directly to both the top surface and a vacuum fixture and the interior chamber which is connectable to a vacuum source is not found persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The reference of Mathus was relied on for its teaching of specific structural limitations. Examiner directs applicant's attention

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to the above rejection of claims 3 and 16-18. In addition, the referece of Moring anticipates claim 1 and has been addressed in the arguments above.

16. Applicant argument that Mohan cannot remedy the defect of Moring because Mohan neither teaches nor suggests orifices that are connected directly to both the top surface of a vacuum fixture and the interior chamber that is connectable to a vacuum source is not found persuasive. Applicant further argues that Mohan does not have a vacuum fixture with a top surface corresponding to the well bottoms or array formation areas. This argument is not found persuasive.

In response to applicant's argument, In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Orfices that are connected directly to both the top surface of the interior chamber has been addressed in the arguments above. The reference of Mohan was relied upon for the teaching of a plurality of caps with inlet and outlet ports, a temperature control element and a vacuum fixture, which are the limitations covered by claims 20-21 and 23-24. Mohan teaches a thermal control block with apertures throughout each one to control the temperature of each reaction vessel. A capping plate with a plurality of caps that corresponds to an array area containing the reaction vessels. The caps overlies and seals the reaction vessels (column 10, lines 58-67). The microplate assembly of the apparatus has a vacuum fixture

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on the surface of the interior chamber (Figure 1) for passing fluid through. Therefore, the reference of Mohan et al appears to teach and suggest the limitations of claim20-21 and 23-24.

17. Applicant argues that Stylli cannot remedy the detect of Moring and does not teach nor suggest anything related to vacuum fixtures, much less containing orifices, wherein each orfice connects directly to both the top surface and the interior chamber. This argument is not found persuasive.

In response to applicant's arguments against the references individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). The limitation wherein each orfice connects directly to both the top surface and the interior chamber has been addressed in the arguments above for claim 1. Stylli was relied upon for the teaching of a peristaltic pump and a motivation for why one of ordinary skill in the art would modifying the teaching of Moring to include this feature is provided in the rejection above.

#### Conclusion

18. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deborah A Davis whose telephone number is

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(571) 272-0818. The examiner can normally be reached on 8-5 Monday thru Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Deborah A. Davis Remsen Bldg. Room 3D58 September 1, 2004

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09/06/04